

Exhibit 1

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

IN RE: '318 PATENT LITIGATION

:
:
:
: Civil Action No. 05-356 (KAJ)
: (Consolidated)
:
:

DEFENDANT TEVA PHARMACEUTICALS USA, INC.'S
AND TEVA PHARMACEUTICAL INDUSTRIES LTD.'S NOTICE OF 30(b)(6)
DEPOSITION TO PLAINTIFFS JANSSEN PHARMACEUTICA N.V.,
AND JANSSEN, L.P.

PLEASE TAKE NOTICE THAT, beginning on May 23, 2006 at 9:30 A.M. at the offices of Kirkland & Ellis, 655 Fifteenth Street, N.W., Washington, D.C. 20005, Defendants Teva Pharmaceuticals U.S.A., Inc. and Teva Pharmaceutical Industries Ltd., ("the Teva Defendants"), will take the deposition of Plaintiffs Janssen Pharmaceutica N.V. and Janssen, L.P., (collectively, "Janssen") as represented by the person(s) most knowledgeable with respect to the subject matter topics identified below and designated to testify on behalf of Janssen Pharmaceutica N.V. and/or Janssen, L.P., pursuant to Federal Rule of Civil Procedure 30(b)(6). The oral examination will be taken before a notary public or other person authorized to administer oaths, and will be recorded by stenographic means and/or videotape. The deposition will continue from day to day until completed with such adjournments as to time and place as may be necessary. You are invited to attend and participate.

The Teva Defendants serve this Notice without waiver of their objections to the deficiencies in Janssen's document production and other discovery responses concerning the

subject matter of the instant Notice, and reserve the right to continue this deposition as necessary in light of any subsequent document production by Janssen.

TOPICS

1. The facts and circumstances under which Janssen first became aware of the article, P.A. Bhasker, *Medical Management of Dementia*, THE ANTISEPTIC, 71(1): 45-47 (1974), including how Janssen learned of it, who was involved in this first awareness, and any evaluation of it conducted by or on behalf of Janssen, then or subsequent to the time Janssen became aware of it.

2. Any evaluation, consideration, or discussion conducted by Janssen to market a galantamine drug product for the treatment of Alzheimer's disease and/or related dementias, including the names and responsibilities of all persons who were involved in the evaluation, consideration, or discussion.

3. The decision to file an application with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a galantamine drug product for the treatment of Alzheimer's disease and/or related dementias.

4. Each and every contribution and/or input that Janssen, or any employee or agent of Janssen has made to the preparation, decision to file, filing and/or prosecution of Janssen's IND and/or NDA, including without limitation any information relating to regulatory procedures and strategies for obtaining regulatory approval of a galantamine drug product for the treatment of mild to moderate Alzheimer's disease and/or related dementias.

5. The facts and circumstances regarding Janssen first becoming aware of galantamine as a treatment for Alzheimer's disease, including without limitation the date on which this occurred and the people involved.

6. The facts and circumstances regarding Janssen first becoming aware of U.S. Patent No. 4,663,318 ("the '318 patent"), including without limitation the date on which this occurred and the people involved.

7. Any consideration or evaluation by Janssen of licensing the '318 patent to any unlicensed party.

8. The factual basis for Janssen's belief that the Teva Defendants engaged in any licensing activity with Dr. Bonnie Davis or Synaptech.

9. Any documents related to the foregoing topics that were either not produced in this case or destroyed and the circumstances under which the documents were withheld from production or destroyed, the identification of all persons with knowledge of the documents and/or their contents, and, in the case of documents destroyed, the dates of the destruction.

10. Janssen Pharmaceutica N.V.'s document retention policies from 1986 to the present.

11. Janssen, L.P.'s document retention policies from 1986 to the present.

12. The identity and location of documents and things concerning the foregoing topics.

13. Persons knowledgeable regarding subject matter of the foregoing topics.

Respectfully submitted,

**YOUNG CONAWAY STARGATT
& TAYLOR, LLP**



John W. Shaw (No. 3362)
Monté T. Squire (No. 4764)
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Ltd.*

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KIRKLAND & ELLIS LLP

655 15th Street, N.W.

Washington, DC 20005-5793

(202) 879-5000

Dated: May 9, 2006

CERTIFICATE OF SERVICE

I, Monté T. Squire, Esquire, hereby certify that on May 9, 2006, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the counsel of record:

BY HAND DELIVERY AND ELECTRONIC MAIL

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Par Pharmaceuticals Companies, Inc.*

I further certify that on May 9, 2006, I caused a copy of the foregoing document to be served on the above-listed counsel of record in the manner indicated and on the following non-registered participants in the manner indicated:

BY ELECTRONIC MAIL

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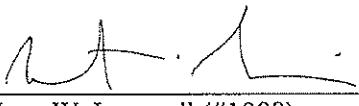
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Attorneys for Teva Pharmaceuticals USA, Inc.
and Teva Pharmaceutical Industries Ltd.

Exhibit 2

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: '318 PATENT LITIGATION :
: :
: Civil Action No. 05-356 (KAJ)
: (Consolidated)
:

DEFENDANTS TEVA PHARMACEUTICALS USA, INC.'S
AND TEVA PHARMACEUTICAL INDUSTRIES LTD.'S
SECOND NOTICE OF 30(b)(6) DEPOSITION TO PLAINTIFFS
JANSSEN PHARMACEUTICA N.V., AND JANSSEN, L.P.

PLEASE TAKE NOTICE THAT, beginning on June 13, 2006 at 9:30 A.M. at the offices of Kirkland & Ellis, 655 Fifteenth Street, N.W., Washington, D.C. 20005, Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd., ("the Teva Defendants"), will take the deposition of Plaintiffs Janssen Pharmaceutica N.V. and Janssen, L.P., (collectively, "Janssen") as represented by the person(s) most knowledgeable with respect to the subject matter topics identified below and designated to testify on behalf of Janssen Pharmaceutica N.V. and/or Janssen, L.P., pursuant to Federal Rule of Civil Procedure 30(b)(6). The oral examination will be taken before a notary public or other person authorized to administer oaths, and will be recorded by stenographic means and/or videotape. The deposition will continue from day to day until completed with such adjournments as to time and place as may be necessary. You are invited to attend and participate.

The Teva Defendants serve this Notice without waiver of their objections to the deficiencies in Janssen's document production and other discovery responses concerning the subject matter of the instant Notice, and reserve the right to continue this deposition as necessary in light of any subsequent document production by Janssen.

TOPICS

1. The factual basis for Plaintiffs' contentions related to any secondary considerations of non-obviousness including the factual basis for the statements set forth in Plaintiffs' response to Teva's Interrogatory No. 15.
2. Information known to Plaintiffs regarding secondary considerations of non-obviousness.
3. Information known to Plaintiffs related to the basis for customer demand of Razadyne tablets.
4. Information known to Plaintiffs related to uses for galantamine tablets.
5. All drug products that compete with Razadyne tablets from launch of the Razadyne drug product through present and their respective market shares in that time frame.
6. Revenues and profits from sales of Razadyne tablets from launch of the Razadyne drug product until present.
7. Costs related to sales of Razadyne tablets including cost of goods sold, marketing of the product, and any other cost or expense related to the sale of Razadyne tablets from launch until present.
8. Marketing and advertising related to Razadyne tablets from launch of the Razadyne drug product until present, including the types and costs of marketing and advertising.
9. Marketing and business plans or strategies related to sales of Razadyne tablets from launch the Razadyne drug product until present, including any plans or strategies related to expected generic competition.
10. Sales, costs, and profit forecasts related to Razadyne tablets including any forecasts or projections related to expected generic competition.
11. Plans or strategies intended to switch Razadyne tablet customers to other drug products.
12. Plaintiffs' investigation into prior art related to the '318 Patent.
13. Communications with third parties related to licensing the '318 Patent, or infringement, validity, or enforceability of the '318 Patent.
14. Licensing of and assignment of rights in of the '318 Patent including actual, proposed, or considered licenses and assignments.

15. Communications, licensing discussions, and any actual or considered litigation between Plaintiffs and Waldheim Pharmazeutika GmbH regarding any United States or foreign patent(s) for the use of galantamine for the treatment of Alzheimer's disease or related dementia, including any arguments set forth by Waldheim Pharmazeutika GmbH regarding any asserted invalidity of such patent(s), any actual or proposed settlement agreements, and any litigation outcomes.

16. Information known to Plaintiffs regarding the following documents: JAN RAZ-0010903-15; JAN RAZ-0010949-50; JAN RAZ-0010965-80; JAN RAZ-0011208-22; JAN RAZ-0011228-34; JAN RAZ-0011244-46; JAN RAZ-0011250-52; SYN RAZ-0000270; SYN RAZ-0000594-595; SYN RAZ-0000721; SYN RAZ-0001076; SYN RAZ-0017576; SYN RAZ-0018791-804; SYN RAZ-0019713; SYN RAZ-0020089-103.

17. The factual basis for Plaintiffs' allegations of standing to bring suit.

18. Any documents related to the foregoing topics that were either not produced in this case or destroyed and the circumstances under which the documents were withheld from production or destroyed, the identification of all persons with knowledge of the documents and/or their contents, and, in the case of documents destroyed, the dates of the destruction.

19. The identity and location of documents and things concerning the foregoing topics.

20. Persons knowledgeable regarding subject matter of the foregoing topics.

Respectfully submitted,



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Edward C. Donovan
Corey J. Manley
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*Attorneys for Teva Pharmaceuticals
USA, Inc. and Teva Pharmaceutical
Industries Ltd.*

May 26, 2006

CERTIFICATE OF SERVICE

I hereby certify that on this 26th day of May, 2006, a true and correct copy of DEFENDANTS TEVA PHARMACEUTICALS USA, INC.'S AND TEVA PHARMACEUTICAL INDUSTRIES LTD.'S SECOND NOTICE OF 30(b)(6) DEPOSITION TO PLAINTIFFS JANSSEN PHARMACEUTICA N.V. AND JANSSEN, L.P. was served, via Federal Express, upon the following:

Christopher N. Sipes, Esq.
Covington & Burling
1201 Pennsylvania Avenue, N.W.
Washington, DC 20004-2401

Steven J. Balick, Esquire
John G. Day, Esquire
ASHBY & GEDDES
222 Delaware Avenue
Wilmington, DE 19801

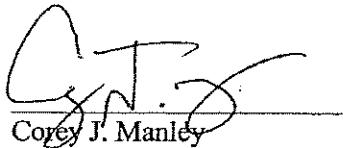

Corey J. Manley

Exhibit 3

From: Calia, Kurt
Sent: Friday, June 09, 2006 3:29 PM
To: Edward C. Donovan (edonovan@kirkland.com); krobinson@kirkland.com
Subject: In re: '318 Patent Infringement Litigation

Ed and Karen:

This is to summarize some of the issues we discussed yesterday during our afternoon teleconference.

First, as to your inquiry about Plaintiffs' availability to provide testimony on the topics identified in the R. 30(b)(6) Notice from Teva that we discussed, we will designate one or more witnesses for testimony on June 23, subject to the objections I explained during our call.

Second, in response to my recent letter regarding Teva's interrogatory responses, you have indicated that the newly-identified individuals in those responses will not be presented as witnesses at trial.

Third, Karen Robinson confirmed on behalf of the defendants that we do have agreement to the stipulation on electronic discovery that I sent in mid-May (seeking a response by May 19). We would appreciate it if you would obtain signatures to that document and return it to me.

Fourth, as to the stipulation on expert discovery, I attach what I originally sent in April, which makes clear that expert discovery as to communications of facts would be fair game, as I indicated yesterday.

We look forward to your response on items 3 and 4 above.



Stipulation on
Expert Discover..

Sincerely,
Kurt G. Calia
Covington & Burling
1201 Pennsylvania Ave., N.W.
Washington, D.C. 20004-2401
202.662.5602 (v); 202.778.5602 (f)
kcalia@cov.com; www.cov.com

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Exhibit 4

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June 14, 2006

VIA EMAIL and FIRST CLASS MAIL

Edward Donovan, Esq.
Kirkland & Ellis, LLP
655 Fifteenth Street, N.W.
Washington, D.C. 20005

Re: In re '318 Patent Litigation, Civil Action No. 05-356-KAJ
(consolidated)

Dear Ed:

This is in response to your June 12, 2006 letter concerning deposition discovery in this case (we will respond to your second June 12, 2006 letter concerning our June 8 teleconference separately).

As explained in my June 6 letter, Plaintiffs' reservation of rights to take additional discovery was a direct result of Teva's refusal to produce its Rule 30(b)(6) witnesses, the last of whom testified on June 8, in response to deposition notices Plaintiffs served on February 21, 2006. Plaintiffs believe Teva's actions violate the Court's Order that defendants complete such depositions by May 12. There is no parallel here, and Teva has no basis for propounding untimely discovery. Your reference to Plaintiffs' document production is to no avail given that the majority of Plaintiffs' documents were produced long ago.

Concerning your questions about Ms. Jaskot's deposition, Plaintiffs expected Teva to comply with the Court's instructions to provide an informed and knowledgeable witness on, among other things, the factual bases for Teva's contentions concerning the objective considerations of non-obviousness in the case. Ms. Jaskot was neither prepared nor knowledgeable on the subject. Given Teva's lengthy delays in responding to this discovery and its failure to comply even with the Court's Order requiring it to produce such a witness by May 12, we believe Teva is now barred from introducing its own knowledge on these subjects.

Similarly, with regard to our inquiry regarding Teva's decision to change from a Paragraph III to a Paragraph IV certification concerning the '318 patent, we have

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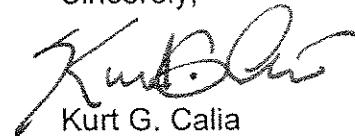
Edward Donovan, Esq.
June 14, 2006
Page 2

long made clear that the filing of a Paragraph III certification (as 10 ANDA filers did) constitutes industry recognition acquiescence in the validity of the '318 patent. Teva's failure to produce a witness informed and knowledgeable with regard to its decision to change from a Paragraph III to a Paragraph IV certification was in violation of the Court's Order, and we believe Teva is now barred from introducing evidence on this subject.

Finally, with regard to Teva's Rule 30(b)(6) notice served by Teva on May 26, I apologize if my e-mail from June 9 was unclear. Plaintiffs will be producing one or more witnesses to respond to topics on both the May 9 and the May 26 notices on Friday, June 23.

Please let me know if you have any questions or concerns.

Sincerely,



Kurt G. Calia

Exhibit 5

-----Original Message-----

From: Calia, Kurt
Sent: Thursday, June 15, 2006 2:59 PM
To: 'Karen Robinson'
Subject: RE: In re: '318 Patent Infringement Litigation

Karen

It is surprising to say the least for Teva to complain about the timing of the R. 30(b) (6) deposition of Janssen in light of the extraordinary delay associated with its own R. 30(b) (6) witnesses, which as you know were not presented for nearly four months after the notices were served. By contrast, Teva will have Janssen's designees within a matter of weeks. Further, Plaintiffs did not obtain final confirmation of which Teva designees were to testify on which topics until May 9 -- a mere 3 days before the depositions were to begin (of course, Ms. Jaskot didn't appear for another month and was not properly prepared even then, as set forth in my letter to Ed Donovan from yesterday). Were Plaintiffs to follow Teva's lead, you would have witnesses to depose the third week in September and an identification of topics just days beforehand.

Having said that, and in further demonstration of the contrast between Plaintiffs diligent discovery efforts and Teva's dilatory conduct, we inform you that Janssen will designate Matthew Zisk to testify as to patent-related topics and Mr. Luc Truyens will testify on scientific issues -- in response to both Teva notices. (I indicated in my letter to Mr. Donovan yesterday that our June 23 witnesses would testify as to both notices.) When we have arrived at our final delineation of witnesses and topics, we will promptly provide you with that information.

Sincerely,
Kurt

Kurt G. Calia
Covington & Burling
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-----Original Message-----

From: Karen Robinson [mailto:krobinson@kirkland.com]
Sent: Wednesday, June 14, 2006 7:24 PM
To: Calia, Kurt
Subject: In re: '318 Patent Infringement Litigation

Dear Kurt:

I write to follow up on your June 9, 2006 email concerning, inter alia, Janssen's 30(b)(6) witnesses offered for deposition on June 23, 2006 in response to Teva's May 9, 2006 Notice of Rule 30(b)(6) Deposition, as well as Ed Donovan's June 12, 2006 letter re the same.

Despite our repeated requests — both during the June 8, 2006 meet and confer and as reflected in Ed's June 12 letter, Janssen has failed to provide any information regarding the noticed 30(b)(6) deposition other than a proposed date. To use your words, the failure to provide this "critical information is manifestly unfair."

Accordingly, absent the immediate identification of the basic information of the identities of Janssen's 30(b)(6) witnesses and the topics on which they will be providing testimony, Teva will seek the assistance of the Court.

In addition, we look forward to the prompt identification of witnesses in response to Teva's May 26, 2006 Notice of Rule 30(b)(6) Deposition.

Regards,

Karen

Karen Robinson
Kirkland & Ellis LLP
202.879.5197

Exhibit 6

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June 19, 2006

VIA EMAIL and FIRST CLASS MAIL

Edward Donovan, Esq.
 Kirkland & Ellis
 655 Fifteenth Street, N.W.
 Washington, D.C. 20005

Re: In re '318 Patent Litigation, Civil Action No. 05-356-KAJ
(consolidated)

Dear Ed:

I am writing to provide information concerning Janssen's designation of Rule 30(b)(6) witnesses for certain topics identified in the May 9 and May 26, 2006 deposition notices served by Teva. As I stated last week, Janssen intends to make Messrs. Luc Truyen and Matthew Zisk available to testify as to certain of these topics. They will be available for deposition in Washington, D.C.

Subject to the objections previously served, Janssen will make Mr. Luc Truyen available as its Rule 30(b)(6) designee on June 23. He will testify as to topic nos. 1-5 (and 9-13, to the extent that they relate to these topics) of the May 9 notice, and topics nos. 1-4 (and 18-20; to the extent that they relate to these topics) of the May 26 notice.

Subject to the objections previously served, Janssen will make Mr. Matthew Zisk available as its R. 30(b)(6) witness on June 29. He will testify as to topic nos. 6-8 (and 9-13, to the extent that they relate to these topics) of the May 9 notice, and topics nos. 1, 2, and 12-17 (and 18-20, to the extent that they relate to these topics) of the May 26 notice.

Janssen has not yet determined who will testify as to the handful of remaining topics of the May 26 R. 30(b)(6) notice, but we anticipate providing that information to you very shortly.

Please let me know if you have any questions or concerns.

COVINGTON & BURLING

Edward Donovan, Esq.
June 19, 2006
Page 2

Sincerely,



Kurt G. Calia

cc: Karen Robinson, Esq. (via email)
Andrew Kay, Esq. (via email)

Exhibit 7

-----Original Message-----

From: Karen Robinson <krobinson@kirkland.com>
To: Calia, Kurt; Edward Donovan <edonovan@kirkland.com>
CC: Andrew Kay <akay@kirkland.com>
Sent: Tue Jun 20 08:11:23 2006
Subject: Re: In re: '318 Patent Infringement Litigation

Kurt,

I write in response to your letter to Ed Donovan sent yesterday evening.

In light of the number of topics designated for Mr. Truyen and the lack of notice on the subject matter about which he will be testifying -just three business days- Teva is unavailable to proceed with Mr. Truyen's deposition on June 23, 2006. Please provide an alternative date for his deposition.

Please do not hesitate to contact me to discuss the issue of scheduling further. I will be traveling this afternoon but will be available in my office this morning as well as by email before 3 pm and after 6 pm.

Regards, Karen

The information contained in this communication is confidential, may be attorney-client privileged, may constitute inside information, and is intended only for the use of the addressee. It is the property of Kirkland & Ellis LLP or Kirkland & Ellis International LLP. Unauthorized use, disclosure or copying of this communication or any part thereof is strictly prohibited and may be unlawful. If you have received this communication in error, please notify us immediately by return e-mail or by e-mail to postmaster@kirkland.com, and destroy this communication and all copies thereof, including all attachments.

Exhibit 8

-----Original Message-----

From: Calia, Kurt
Sent: Tuesday, June 20, 2006 9:29 AM
To: 'Karen Robinson'; Edward Donovan
Cc: Andrew Kay
Subject: RE: In re: '318 Patent Infringement Litigation

Karen:

The only day between now and the close of fact discovery that Mr. Truyens is available is Friday, June 23, and so it will have to go forward on that date. As you know, Teva delayed until May 26 to notice many of its R. 30(b)(6) topics, and so it can hardly claim a need for more time. We also note that Plaintiffs provided Teva greater notice than Teva for its R. 30(b)(6) notices, and, of course, Plaintiffs made our witnesses available in a much, much shorter time frame in full compliance with the scheduling order. This is in contrast to Teva who ignored the Court's order that defendants make its witnesses available by May 12, ignored the Court's request during the status conference that the defendants "move up" any remaining depositions, and didn't present a witness for topics noticed on February 21 until June 8. Furthermore, we provided you with a subject area description of the designated topics for Mr. Truyens (and Mr. Zisk) last week. With at least four partners at your firm on this case, it is hard to believe you cannot be available for the deposition on Friday, and we believe that the Court will expect the parties to complete discovery within the current schedule. We are not at liberty to ignore the Court's scheduling order which requires fact discovery to be completed on June 30, and Mr. Truyens is not available on any other date.

Sincerely,
Kurt G. Calia
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-----Original Message-----

From: Karen Robinson [<mailto:krobinson@kirkland.com>]
Sent: Tuesday, June 20, 2006 8:11 AM
To: Calia, Kurt; Edward Donovan
Cc: Andrew Kay
Subject: Re: In re: '318 Patent Infringement Litigation

Kurt,

I write in response to your letter to Ed Donovan sent yesterday evening.

In light of the number of topics designated for Mr. Truyen and the lack of notice on the subject matter about which he will be testifying -just three business days- Teva is unavailable to proceed with Mr. Truyen's deposition on June 23, 2006. Please provide an alternative date for his deposition.

Please do not hesitate to contact me to discuss the issue of scheduling further. I will be traveling this afternoon but will be available in my office this morning as well as by email before 3 pm and after 6 pm.

Regards, Karen

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Exhibit 9

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June 30, 2006

VIA EMAIL and FIRST CLASS MAIL

Karen Robinson, Esq.
Kirkland & Ellis, LLP
655 Fifteenth Street, N.W.
Washington, D.C. 20005

Re: In re '318 Patent Litigation, Civil Action No. 05-356-KAJ
(consolidated)

Dear Karen:

This is in response to your June 27, 2006 letter concerning depositions in this matter. You are incorrect in stating that we have "discussed" Teva's unavailability to take the deposition of Janssen's designee, Mr. Truyen, on June 23. To the contrary, you have never explained why none of the approximately nine Teva lawyers that have appeared in this case could not be available on that date, despite Plaintiffs' identification of the June 23 deposition date on June 14.

As stated in my earlier correspondence, we simply are not at liberty to ignore the Court's discovery deadlines in this case (deadlines that defendants sought and obtained) and agree that discovery will go beyond today's deadline. And because Mr. Truyen is not available until late July or early August as I previously stated, this is not a simple matter of postponing a deposition by mere days. We proposed the June 23 date because it was the only date that Mr. Truyen was available for a deposition in this matter before leaving the country for a month.

Your post facto claim of unavailability based on Janssen's supplemental document production does not square with the facts. Teva rejected the June 23 date before Janssen's supplemental document production was sent to you (which we hand delivered several days in advance of Mr. Truyen's deposition – in contrast to the defendants' strategy of producing documents the day before or even during depositions in this matter). Janssen's supplemental production amounted to less than 1% of its overall production in this matter, and it is hard to believe that the collective resources of its counsel could not be mustered to review less than a box of documents in advance of the deposition. As to the specific "life cycle" document you mention in your letter, that

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Karen Robinson, Esq.
June 30, 2006
Page 2

document was produced upon completion of the re-review of privileged documents that was recently conducted. As you know, Plaintiffs are not the only party to release documents off of privilege logs (as demonstrated by the fact that Alphapharm released more than half of the documents it had originally withheld on privilege grounds as recently as June 19). (We further note that the "life cycle" document that you appear to name in your letter is a Janssen document, and so we reject your statement that Teva needed that document to take Dr. Davis's deposition, who as you know is not an Janssen employee.)

As to Janssen's choice of Mr. Truyen as designee, that is, of course, a matter that is entirely within Janssen's discretion, and we selected him as the person best able to provide the discovery sought by Teva. That none of Teva's many lawyers saw fit to make themselves available on the date of Mr. Truyen's availability does not warrant a conclusion that Janssen should have designated a different witness.

Your reliance on the deposition date for Dr. Rosenberg of Alphapharm is misplaced. First of all, he was not a R. 30(b)(6) designee at all, but rather is appearing in his individual capacity as a replacement for Mr. Self, who we understand was injured in an auto accident and is unable to appear for deposition for some time. No parallel can be drawn between the extraordinary circumstances associated with Dr. Rosenberg's replacement deposition and Teva's unexplained inability to appear for a deposition during the discovery period. Moreover, the deposition of Dr. Rosenberg will occur on July 6 – sufficiently in advance of the opening round of expert reports in this matter so as to not require any modification of the schedule. Because Mr. Truyen is not available until late July or early August at the earliest, taking his deposition at that late date would have implications for the schedule – a fact overlooked by your letter.

As you know, Teva served its deposition notices very late in discovery, and it knew that Janssen's witnesses would have to appear during the last two weeks of the discovery period (indeed, Teva's second notice did not seek deposition testimony until June 13.) Accordingly, having inexplicably delayed the initiation of discovery for so long, Teva should have been in a position to dedicate the necessary resources to completing fact discovery during the period set by the Court at defendants' collective insistence. That it chose not to do so does not warrant a conclusion that Plaintiffs' should accede to the demands of Teva's counsel (still unexplained) and set a deposition out-of-time in such fashion as to have implications for the overall schedule in this matter.

For the foregoing reasons, we do not believe that we have an obligation to make witnesses available after the discovery period. Please let me know if you have any questions or concerns.

COVINGTON & BURLING

Karen Robinson, Esq.
June 30, 2006
Page 3

Sincerely,



Kurt G. Calia

cc: Steven Balick, Esq. (via email)

Exhibit 10

SHEET 1

1

1 IN THE UNITED STATES DISTRICT COURT
2 IN AND FOR THE DISTRICT OF DELAWARE

4 IN RE: '318 PATENT : CIVIL ACTION
INFRINGEMENT LITIGATION, : NO. 05-356 (KAJ)
5 : (Consolidated)

BEFORE: HONORABLE KENT A. JORDAN, U.S.D.C.J.

11 APPEARANCES:

ASHBY & GEDDES
BY: STEVEN J. BALICK, ESQ.

14 -and-

15 COVINGTON & BURLING
16 BY: GEORGE F. PAPPAS, ESQ.,
17 CHRISTOPHER N. SIPES, ESQ., and
KURT G. CALIA, ESQ.
(Washington, District of Columbia)

18

22 Counsel for Janssen Pharmaceutica
N.V., Janssen, L.P. and Synaptech Inc.

24 Brian P. Gaffigan
25 Registered Merit Reporter

SHEET 4

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1 they did not exist until after we had collected our ANDA
 2 documents and what they relate to are things that relate to
 3 bioequivalence.

4 THE COURT: Talk to me now for just a minute --
 5 and I'll give others on the defense side to chime in here if
 6 they want, but speak to me about the fundamental issue which
 7 the plaintiffs have raised, which is regardless of who hit
 8 who, making the discovery cutoff here seems chancy to them.
 9 What do you think about that? If you disagree, why do you
 10 disagree?

11 MR. DONOVAN: I disagree, Your Honor. The fact
 12 discovery ends the end of June. The only outstanding
 13 depositions that I'm aware of that plaintiffs have even
 14 served are Teva 30(b)(6) which are not yet satisfied, and it
 15 may be that one of the other defendants has not yet put
 16 forward a witness on one of those 30(b)(6) witnesses, but
 17 there are no other outstanding deposition notices. Maybe
 18 they intend to serve more, but they haven't done that.

19 If anything, it's on our end. We'll be getting
 20 our first round of 30(b)(6) depositions on some of the
 21 parties. We're just starting that. If anybody is sort of
 22 in a pinch, we are. And if anybody is getting a lot of
 23 documents at the end of discovery, I don't think there is
 24 any way that the burden doesn't fall there on plaintiffs.
 25 We are just getting documents dumped on us as it relates to

1 landscape will look like, other various assumptions that
 2 affect the generic market for Barr; not the brand market,
 3 just the generic market. Barr had produced every version
 4 of the SureLock model that it had available to the company
 5 that it could locate well in advance of Mr. Sawyer's
 6 deposition.

7 On the day before the deposition, my client
 8 indicated that they could print out another version of the
 9 SureLock model. I wanted to make sure the plaintiff had
 10 what was used being the most current version of the SureLock
 11 model at the time of my client's deposition, particularly
 12 in light of the discussions that happened regarding
 13 Mr. Harper's deposition and wanted to make sure that we
 14 could foreclose any issues there. We sent a copy of that
 15 over.

16 Mr. Pappas spent six hours and 54 minutes of
 17 his seven hours of allotted time questioning Mr. Sawyer
 18 predominantly about each and every SureLock model that
 19 defendants have produced -- excuse me -- that Barr had
 20 produced. Towards the end of the deposition, Mr. Pappas
 21 asked a question along the lines of whether or not Barr's
 22 assumptions were going to change about the competitive
 23 landscape in light of learning that there were multiple
 24 filers on the products. We had some discussion about
 25 objections and privilege. Mr. Sawyer indicated that the

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1 the issue of marketing. We just saw for the first time
 2 their contentions on secondary considerations and
 3 nonobviousness as required in the interrogatories. We had
 4 asked that interrogatory last fall. We were promised a
 5 response in February and we just got it.

6 Now, that said, we've got enough time. We'll
 7 get this done. This happens in every case and there aren't
 8 a lot of scheduled depositions out there that is going to
 9 take up a lot of time. So we're pretty confident we can get
 10 this all done. We're going to work hard but we can get it
 11 done.

12 THE COURT: Now, without my going through
 13 defendant-by-defendant name, let me ask if there are any
 14 other defendants represented on the call who want to chime
 15 in on this point.

16 MS. ULRICH: Your Honor, this is Lynn Ulrich,
 17 counsel for Barr Laboratories. I would like to address
 18 Mr. Pappas' comments relating to Barr's 30(b)(6) witness on
 19 sales and marketing.

20 I have to disagree with Mr. Pappas's recitation
 21 of the facts. For the Court's benefit, Barr creates a
 22 document they call a SureLock model. It's about a 306-page
 23 document. It contains INS data, publicly available
 24 information, and Barr makes certain assumptions about when
 25 they're going to launch their product, what the competitive

13

1 SureLock model will continue to change. It's updated
 2 periodically. There is no set reason why it will change but
 3 that he was going to go back and talk with the president of
 4 the company and others in the department and look at the
 5 assumptions to see if they were going to change in light of
 6 Barr learning there were multiple filers on this drug.

7 At that point, Mr. Pappas said he had the right
 8 to take Mr. Sawyer's deposition again. They viewed him as
 9 being unprepared as a 30(b)(6) witness. My position then
 10 is the same as today, which is that Mr. Sawyer was more than
 11 prepared as a 30(b)(6) witness with respect to Barr's sales
 12 and marketing at the time of the deposition.

13 Mr. Calia and I have had discussions in writing
 14 regarding this issue. I had told him specifically that Barr
 15 would be willing to consider making Mr. Sawyer available
 16 again for one hour, between post-deposition and before
 17 trial --

18 THE COURT: You are going to -- I've got to
 19 interrupt you.

20 MS. ULRICH: -- may change again.

21 THE COURT: Hold on a second. You are going
 22 to have to identify for me. When you say "Mr. Calia," I'm
 23 assuming that is one of Mr. Pappas' colleagues, somebody
 24 on the plaintiffs' side, but you are going to have to be
 25 specific because I don't know who the many attorneys are in

SHEET 7

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1 anything in the way to try to delay discovery in this case,
2 with that intention in mind at all.

3 THE COURT: And I don't mean to imply you were.
4 So please, if anything I said bore that implication, forgive
5 me. All I'm trying to do is emphasize to everybody there
6 ought to be nothing going on now but trying to get discovery
7 done as rapidly as possible. No strategic moves, just get
8 the discovery done, please. All right?

9 All right. Last chance. Does anybody on the
10 defense side need to weigh in?

11 MS. ULRICH: Your Honor, this is Lynn Ulrich
12 from Barr Laboratories.

13 I would just say I disagree with Ms. Pappas'
14 position relating to Mr. Sawyer. And I will continue to
15 work with Mr. Pappas to try to get this issue resolved.

16 THE COURT: I'm glad to hear you will be working
17 together. Good.

18 All right. Well, thanks for your time today. I
19 appreciate the letters that were sent in with the update.
20 Hopefully when we speak to each other next, it will be with
21 discovery having been concluded and everybody satisfied that
22 they had their fair shot.

23 MR. PAPPAS: Your Honor, in that regard, on
24 behalf of the plaintiffs, could we respectfully request you
25 set a status conference in about three weeks for us to take

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1 stock of where we are?

2 THE COURT: Yes, you can sure make that request.
3 And you know what? I'll take that under advisement. You
4 might well hear from us; okay?

5 MR. PAPPAS: Very well, Your Honor. Thanks.

6 THE COURT: All right. Thanks.

7 MS. ULRICH: Thank you, Your Honor.

8 MR. DONOVAN: Thank you, Your Honor.

9 (Telephone conference ends at 5:05 p.m.)

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Exhibit 11

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: '318 PATENT) C.A. No. 05-356-KAJ
INFRINGEMENT LITIGATION) (consolidated)
)

**PLAINTIFFS JANSSEN PHARMACEUTICA N.V.'S, JANSSEN, L.P.'S, AND
SYNAPTECH, INC.'S OBJECTIONS AND RESPONSE TO DEFENDANTS
TEVA PHARMACEUTICALS, USA, INC.'S AND TEVA PHARMACEUTICAL
INDUSTRIES LTD'S SECOND SET OF INTERROGATORIES**

Pursuant to Federal Rule 33 of Civil Procedure and the Local Civil Rules of this Court, Plaintiffs Janssen Pharmaceutica N.V., Janssen L.P., and Synaptech, Inc., (collectively, "Plaintiffs") hereby object and respond to Defendants Teva Pharmaceuticals, USA, Inc.'s and Teva Pharmaceutical Industries Ltd's (collectively, "Defendants" or "Teva") Second Set of Interrogatories (the "interrogatories"). Plaintiffs' response to these interrogatories is without prejudice to, and does not constitute a waiver of, Plaintiffs' rights to rely on other documents or information at trial. Plaintiffs also reserve the right under Rule 26(e) to supplement this response.

General Objections

A. Plaintiffs object to each of Defendants' interrogatories to the extent it seeks information that is (i) subject to the attorney-client privilege; (ii) subject to attorney work product immunity; and/or (iii) subject to any other privilege. Plaintiffs hereby claim such privileges and immunities to the extent implicated by each interrogatory, and exclude privileged and protected information from their responses. Any disclosure of such privileged or immunized information is inadvertent and is not intended to waive those privileges and immunities.

B. Plaintiffs object to the interrogatories on the grounds and to the extent that they call for the provision of information that is overbroad, unduly burdensome, and not relevant to the subject matter of the pending action or that is not reasonably calculated to lead to the discovery of admissible evidence.

C. Plaintiffs object to the interrogatories, and to the Definitions and Instructions therein, on the grounds and to the extent that they purport to impose any obligation on Plaintiffs that is beyond the scope of Rules 26 and 33 of the Federal Rules of Civil Procedure or other applicable law.

D. Plaintiffs' written responses and production of documents are based on information presently available to and located by Plaintiffs and their attorneys. As Plaintiffs have not completed their investigation of the facts relating to this case, their discovery in this action, or their preparation for trial, Plaintiffs' written responses and production of documents are made without prejudice to their right to supplement or amend their written responses and production of documents and to present evidence discovered hereafter at trial.

E. Plaintiffs object to the interrogatories to the extent that they purport to require disclosure or production of information subject to confidentiality requirements or expectations between Plaintiffs and any third party.

F. Plaintiffs' responses are provided without prejudice to Plaintiffs' right to oppose the admissibility or use of any document produced by Plaintiffs or any other party or third party in this case. Plaintiffs' production of a document in response to these interrogatories should not be taken as an admission concerning its authenticity, relevance, or admissibility. Further, any statement in these responses that Plaintiffs will produce

any non-privileged responsive documents that are discovered in a reasonable search of files within their possession, custody, or control should not be construed as an assertion that any such documents in fact exist; such a statement means only that Plaintiffs will conduct a reasonable, good-faith search for any such documents and will produce any non-privileged responsive documents that are found.

Plaintiffs reserve their right to require the return of any privileged document that may inadvertently be produced in response to these interrogatories. Plaintiffs also reserve the right to designate (or re-designate) any confidential document that may inadvertently be produced without the appropriate confidentiality designation.

G. Plaintiffs' objections and responses to the interrogatories, including any production of related documents, are not intended to waive or prejudice any objections Plaintiffs may assert now or in the future, including, without limitation, objections as to the relevance of the subject matter of any interrogatory or document request, or to the admissibility of any response or document or category of responses or documents at trial. Plaintiffs expressly reserve any and all rights and privileges under the Federal Rules of Civil Procedure, the Federal Rules of Evidence and any other law or rule, and the failure to assert such rights and privileges or the inadvertent disclosure by Plaintiffs of information protected by such rights or privileges shall not constitute a waiver thereof, either with respect to these responses or with respect to any future discovery responses or objections.

H. Plaintiffs object to the interrogatories to the extent that the burden or expense of the proposed discovery outweighs its likely benefit, taking into account the

needs of the case, the parties' resources, the importance of the issues at stake in the litigation, and the importance of the proposed discovery in resolving the issues.

I. Plaintiffs object to Defendants' definition of "you," "your," "Janssen," "Janssen Pharmaceutica N.V.," "Janssen, L.P.," and "Synaptech" as confusing, overly broad, and unduly burdensome. For purposes of these interrogatories, "you" and "your" shall refer to Janssen Pharmaceutica N.V., Janssen, L.P., and Synaptech, Inc., named Plaintiffs to this litigation. "Janssen" shall refer to the named Plaintiffs, Janssen Pharmaceutica, N.V. or Janssen, L.P., either collectively or individually, as specified in each of Plaintiffs' responses. Synaptech shall refer to Synaptech, Inc.

J. Plaintiffs object to these interrogatories to the extent they call for the collective knowledge and collective answer of separate entities.

K. Plaintiffs object to the interrogatories to the extent that they seek to impose an obligation on Plaintiffs to locate, obtain, and produce documents and things that are in the public domain, and therefore, are equally accessible to Defendants.

Specific Objections and Responses

Interrogatory No. 10

State the basis for Plaintiffs' disagreement, if any, with the positions set forth in Defendants' first supplemental response to Plaintiffs' Interrogatory No. 2, including without limitation the identity of all witnesses and Documents on which Plaintiffs rely as a basis for their disagreement.

Response:

In addition to the foregoing General Objections, Plaintiffs object that the interrogatory prematurely calls for information within the scope of expert discovery, and Plaintiffs reserve their rights to supplement and enlarge their positions and contentions concerning the subject matter of this interrogatory in the course of expert disclosure and testimony. Plaintiffs also object that discovery is ongoing, Defendants have refused to date to produce a witness in response to Plaintiffs' notice of deposition under Rule 30(b)(6) concerning Defendants' invalidity contentions, and Defendants' "first supplemental response to Plaintiffs' Interrogatory No. 2" was recently superseded by Defendants' Second Supplemental Response to Interrogatory No. 2, which was served on Plaintiffs on May 10, 2006. With respect to the identity of witnesses and documents, Plaintiffs refer Defendants to Plaintiffs' disclosures under Rule 26(a), which Plaintiffs reserve the right to supplement or amend.

Without waiving the foregoing objections, Plaintiffs disagree with the contentions set forth in Defendants' first and second supplemental responses to Plaintiffs' Interrogatory No. 2 and state that those contentions fail to support Defendants' asserted defense that Claims 1 and 4 of the '318 patent are invalid.

With regard to Defendants' asserted section 102(b) defense, the sole purported reference cited by Defendants in support of that defense – P.A. Bhasker, *Medical Management of Dementia*, THE ANTISEPTIC, 71(1):45-47 (1974) ("Bhasker") – does not constitute a written description of the invention claimed in Claims 1 and 4 of the '318 patent. Bhasker does not describe the use of galantamine to treat Alzheimer's disease, let alone dosage forms or amounts for such treatment, and to the contrary

describes progressive dementias as untreatable. The text of Bhasker thus teaches away from the invention claimed in Claims 1 and 4 of the '318 patent. (It is also noteworthy that the vast majority of the Defendants' paragraph IV notices concerning their allegations of invalidity did not even assert section 102 as a defense.) In addition, Defendants' responses fail to demonstrate that Bhasker was sufficiently accessible to the public interested in the art relevant to Claims 1 and 4 of the '318 patent, and Plaintiffs are unaware of Bhasker either being cited in any relevant literature or indexed in any relevant way prior to the filing of the application leading to the '318 patent.

With regard to Defendants' asserted section 103 defense, Defendants' response fails to support Defendants' contention that Claims 1 and 4 of the '318 patent are invalid for obviousness. Defendants' response fails to demonstrate either a motivation to combine references or a reasonable expectation of success from doing so. Defendants' response asserts that "these prior art articles teach the use of acetylcholinesterase inhibitors — a class of drugs that includes physostigmine and galantamine — and physostigmine specifically to treat Alzheimer's disease." However, the prior art teaches no such thing. To the contrary, there was considerable skepticism in the art about pharmacologic approaches to treatment of Alzheimer's generally, and about cholinesterase inhibitors specifically, and Plaintiffs refer Defendants to the Response to Interrogatory No. 15.

This skepticism is reflected even in the references cited in Defendants' response. Thus, for example, Mohs et al., *Intravenous and Oral Physostigmine in Alzheimer's Disease*, INTERDISCIPL. TOPICS. GERONT. 20: 140-52 (1985) observes that "there are no pharmacologic agents that have convincingly been demonstrated to be

effective in treating patients with Alzheimer's disease (AD)." And tellingly, that reference was published too late to qualify as prior art. And the many references cited in Defendants' response concerning the cholinesterase properties of galantamine also refute Defendants' contentions, as not one of those references even hints at the possible use of galantamine to treat Alzheimer's. Obviousness is also refuted by the many objective considerations of non-obviousness, all of which convincingly show that the use of galantamine to treat Alzheimer's as claimed in Claims 1 and 4 of the '318 patent was not obvious.

With regard to Defendants' asserted section 112, ¶ 1 defense, Defendants' assertion that the '318 patent is not enabling is contradicted by Defendants' own allegations of obviousness under section 103. The specification of the '318 patent teaches one of skill in the art to make and use the invention, and the practical utility of galantamine as a treatment for Alzheimer's was confirmed both by the animal studies described in the patent ('318 patent, col. 2, lns. 45-57), *see, e.g.*, Sweeney et al., *A Long-Acting Cholinesterase Inhibitor Reverses Spatial Memory Deficits in Mice*, PHARMACOLOGY BIOCHEMISTRY & BEHAVIOR 31: 141-47 (1988), and ultimately in human clinical trials reviewed by FDA. In addition, the manner of making and using the dosing regimens claimed in Claims 1 and 4 of the patent are similarly enabled by the disclosure of the '318 patent, including the practice of titrating to a safe and effective dose, *e.g.* '318 patent, col. 1, lns. 64-66.

Interrogatory No. 11

Identify each person that Plaintiffs have consulted or plan to consult as an expert or consultant in this action, and for each such person describe: (a) the subject matter on which the expert or consultant is expected to provide an opinion or advice; (b) the substance of the opinion(s) to be provided or advice to be rendered; (c) the factual bases for such opinion(s) or advice; (d) the documents, data or other information relied upon or considered by the expert or consultant in rendering such opinion(s) or advice; (e) the expert's or consultant's educational and professional experience; (f) the documents provided to and/or prepared by the expert or consultant, including drafts; and (g) the compensation, if any, being paid to the expert or consultant for his or her services.

Response:

In addition to the foregoing General Objections, Plaintiffs object to this interrogatory as premature in calling for the identification of persons that Plaintiffs "have consulted or plan to consult as an expert or consultant in this action." Plaintiffs also object to this interrogatory as improperly intruding into matters covered by the attorney-client privilege and work product doctrine. Plaintiffs will make timely and adequate disclosures under Rule 26(a)(2) and the Court's Revised Scheduling Order of January 12, 2006.

Interrogatory No. 12

Identify each person, whether employees of Plaintiffs or third parties involved in the evaluation, consideration, or discussion at or by Plaintiffs to develop Plaintiffs' Reminyl® / Razadyne® drug product covered by Plaintiffs NDA No. 21-169 and for each such person describe: (a) the responsibilities of that person and (b) that person's involvement in such evaluation, consideration, or discussion.

Response:

In addition to the foregoing General Objections, Plaintiffs object on the ground that identifying "each person, whether employees of Plaintiffs or third parties involved in the evaluation, consideration, or discussion at or by Plaintiffs to develop Plaintiffs' Reminyl® / Razadyne® drug product" would be unduly burdensome. Insofar

as the interrogatory seeks information concerning third parties, Plaintiffs further object that the interrogatory calls for information outside the knowledge and control of Plaintiffs. Subject to and without waiving any objections, Plaintiffs identify the following individuals: (1) Dr. Bonnie M. Davis, responsible for the invention of the '318 patent and responsible for and involved in licensing of the patent; (2) Jos Laurijssen, responsible for and involved in patent licensing, including licensing of the '318 patent; (3) Alain Raoult, responsible for and involved in drug development, including Reminyl® / Razadyne®; (4) Luc Truyen, responsible for and involved in regulatory approval, including approval for Reminyl® / Razadyne®; and (5) Filip Verhoeven, responsible for and involved in patent licensing, including licensing of the '318 patent. Plaintiffs reserve the right to supplement or amend this Response and Plaintiffs' disclosures under Rule 26.

Interrogatory No. 13

Identify each person, whether employees of Plaintiffs or third parties, involved in the creation or submission of Plaintiffs NDA No. 21-169 or the corresponding IND, and for each such person describe their respective roles.

Response:

In addition to the foregoing General Objections, Plaintiffs object on the ground that identifying "each person" involved in the regulatory submissions identified in the interrogatory would be unduly burdensome. Subject to this objection, Plaintiffs identify Luc Truyen as an employee involved in the creation or submission of Plaintiffs' NDA No. 21-169 or the corresponding IND. For the names of additional persons involved in the NDA and IND submissions that are the subject of this interrogatory,

Plaintiffs refer Defendants to certain regulatory submissions produced in this litigation which bear the Bates numbers JAN RAZ 12667-42967 and JAN RAZ 163956-174471.

Interrogatory No. 14

Identify each instance where P.A. Bhasker, *Medical Management of Dementia*, THE ANTISEPTIC, 71(1): 45-47 (1974) was identified, evaluated, considered, or discussed by any person, whether employees of Plaintiffs or third parties in connection with the decision to file the patent application or the prosecution of the patent application that resulted in the '318 patent, and for each instance identify the person(s) involved; that person's involvement in such identification, evaluation, consideration, or discussion; and the substance of such identification, evaluation, consideration, or discussion.

Response:

The article referenced in this interrogatory, P.A. Bhasker, *Medical Management of Dementia*, THE ANTISEPTIC, 71(1): 45-47 (1974), was not identified, evaluated, considered, or discussed by any person, whether employees of Plaintiffs or third parties, in connection with the decision to file the patent application or the prosecution of the patent application that resulted in the '318 patent.

Interrogatory No. 15

Describe Plaintiffs' contentions regarding the applicability of each of the secondary considerations of non-obviousness as articulated by the Court of Appeals for the Federal Circuit, including but not limited to unexpected results, commercial success, failure of others, long-felt need, copying, skepticism in the art, licensing, and third party praise, to Defendants' allegation of invalidity of the '318 patent, and identify all documents bearing on such secondary considerations and the five (5) most knowledgeable persons concerning Plaintiffs' contentions.

Response:

In addition to the foregoing General Objections, Plaintiffs object that the interrogatory prematurely calls for information within the scope of expert discovery, and Plaintiffs reserve their rights to supplement and enlarge their positions and contentions concerning the subject matter of this interrogatory in the course of expert disclosure and

testimony. Plaintiffs also object that discovery is ongoing, and that despite repeated requests Defendants have failed to produce documents relevant to the objective considerations of nonobviousness, including licensing and failure of others. Plaintiffs accordingly reserve their right to supplement their response to this interrogatory.

Without waiving the foregoing objections, Plaintiffs contend that the validity of the '318 patent is supported by, among other things, objective considerations of nonobviousness, including without limitation: long felt need, failure of others, skepticism, recognition in the industry including licensing, copying, and acquiescence, and unexpected results.

Before the 1960s, senility was seen as a normal part of aging, and the term Alzheimer's Disease was typically reserved for the rare, presenile onset dementia. However, following the landmark British cliniconeuropathologic correlation studies in the 1960s, the epidemiology of the disease was redefined and Senile Dementia of the Alzheimer's Type was recognized as epidemic. It was also recognized that the epidemic, and its impact on society, was growing dramatically as the population aged and that there were no effective treatments for the cognitive decline that is the core feature of Alzheimer's Disease (used herein to encompass both presenile onset Alzheimer's and Senile Dementia of the Alzheimer's Type). The long felt need for such a treatment dates back at least to that time, evidenced by a rapidly expanding focus on Alzheimer's research and the search for treatments, including the establishment of the National Institute on Aging, formation of the Alzheimer's Disease and Related Disorders Association (now the Alzheimer's Association), and the Alzheimer's Disease Research Centers. Yet despite a long felt need for an effective treatment for the cognitive decline associated with

Alzheimer's Disease, no such treatment had been found by January 1986, when Dr. Bonnie Davis filed the patent application that ultimately was issued as the '318 patent.

The lack of a treatment did not come from lack of trying. To the contrary, many routes to a treatment, and many possible treatments, had been tried without success. Indeed, those failures continued up to the date Razadyne® – the commercial embodiment of the '318 patent – was approved by FDA. Those failures include:

- tofranil
- prozac and other serotonin reuptake inhibitors
- guanfacine
- yohimbine
- selegiline
- rasagiline
- chelation therapy (therapy to remove aluminum from patient and blood and tissue)
- gingko biloba
- prednisone
- estrogen therapy and estradiol
- papaverine
- cyclandalate
- isoxsuprime
- ergaloid mesylates
- piracetam
- choline
- lecithin
- xanomeline
- arecoline
- bethanechol
- physostigmine
- alaproctate
- citalopram
- trazdone
- pentoxyfyllin
- nafronyl
- sabeluzole
- ACTH (and other neuropeptides)

Not surprising given the number of failures, there was considerable skepticism of pharmacologic treatments for Alzheimer's Disease. Thus, for example,

Leo Hollister of Stanford University wrote in 1985 that “[t]reatment of [Alzheimer’s Disease] is presently far from satisfactory. Many physicians have taken such a negative view of the prospects that they refuse to try anything.” L.E. Hollister, *Survey of Treatment Attempts in Senile Dementia of the Alzheimer Type*, in C.G. Gottfries, ed., **NORMAL AGING, ALZHEIMER’S DISEASE AND SENILE DEMENTIA: ASPECTS ON ETIOLOGY, PATHOGENESIS, DIAGNOSIS AND TREATMENT** 299-306 (Editions de l’Université de Bruxelles: 1985). Professor Hollister’s article also provides a survey of treatment strategies at the time, all of which save the cholinesterase inhibitors have failed.

In addition to this general skepticism, there was also considerable skepticism in the art concerning treatment strategies focused on the cholinergic system, which galantamine as a cholinesterase inhibitor is. By the date of application, Alzheimer’s Disease was known to be associated with a wide variety of neurologic disorders and neurochemical deficiencies, including for example, acetylcholine, norepinephrin, serotonin, somatostatin, vasopressin, and β -endorphin. Many believed that a therapeutic strategy focused on a single neurotransmitter was doomed to fail, a belief strengthened by the failure of choline precursor therapy. Instead, the range of disorders and deficits associated with Alzheimer’s Disease encouraged many to pursue (fruitlessly, as it turned out) drugs that were thought to provide broader neuroprotective or cognition enhancing properties, such as the so-called “nootropics.”

What is more, there were many who were particularly skeptical about the possibility of developing a successful treatment for Alzheimer’s Disease using a cholinesterase inhibitor. As indicated above, the perceived breadth of the disorder and degradation of the cholinergic system made many skeptical that a cholinergic approach,

including use of a cholinesterase inhibitor, would afford any therapeutic benefit. In addition, there were concerns that cholinesterase inhibitors would have too small a therapeutic index – exacerbated by the frail nature of typical Alzheimer's patients, would lack specificity, and would impair the phasic nature of synaptic firing. Concern was expressed that cholinesterase inhibitors might in fact promote degradation of the cholinergic system, either through cholinesterase up-regulation or through depletion of free choline at nerve terminals and consequent acceleration of the hydrolysis of membrane phospholipids.

Skepticism of cholinesterase inhibitors was expressed both at the time of application and later, when Dr. Bonnie Davis attempted to interest pharmaceutical companies in developing galantamine as a treatment for Alzheimer's, as evidenced, for example, with Wyeth Laboratories' lack of interest in galantamine until after FDA approved tacrine (another cholinesterase inhibitor) in 1993. (See, generally, transcript of deposition of Wyeth under Rule 30(b)(6) and exhibits thereto.) Others include: Mitsui Pharmaceuticals, Inc., which decided not to develop a galantamine product because it perceived a poor correlation between animal data and clinical efficacy in patients with Alzheimer's Disease and its fear of unexpected adverse effects in patients during long-term treatment (SYN RAZ-0000594-595); Boehringer Ingelheim KG, which asserted that galantamine did "not have the biochemical and pharmacological profile which [Boehringer] consider[ed] essential for [galantamine's] potential use in the treatment of Alzheimer's disease" (SYN RAZ-0001076; SYN RAZ-0000270); E.R. Squibb & Sons, which expressed concern that "the therapeutic benefit and long term safety and tolerability of galanthamine is still a matter for speculation" (SYN RAZ-0000721); and

the Upjohn Company, which stated that it was "already fully committed to other mechanistic approaches to Alzheimer's Disease which [Upjohn] consider[ed] more promising than that offered by galantamine" (SYN RAZ-0017576).

Moreover, even for those interested in developing an Alzheimer's treatment using a cholinesterase inhibitor, many failed. Failed cholinesterase inhibitors include:

- metrifonate
- huperzine
- physostigmine and physostigmine SR
- hyptylphysostigmine
- pyridostigmine
- edrophonium
- synapton
- SM 1088
- zifrosilone
- amiridin
- velnacrine
- phenserine
- ganstigmine
- quilostigmine
- suronacrine
- TAK 147
- epistigmine
- methanesulfonyl fluoride
- CP 118,954
- KA 672
- Gen 2819

In addition, Razadyne® – the commercial embodiment of the '318 patent – has been a tremendous commercial success, whether measured by prescriptions, total sales, or overall profitability. The success of Razadyne® is shown by the marketing and commercial documents that have been and will be produced by Plaintiffs, as well as by Defendants' own sales projections and marketing studies (in addition to their

individual decisions to develop and seek approval for generic copies of the Razadyne® product).

The validity of the '318 patent has been recognized in the industry, both through licensing, copying, and acquiescence of others. As for licensing, both Ciba Geigy (now Novartis) and Janssen licensed the '318 patent in order to develop a galantamine drug product for treatment of Alzheimer's Disease in the United States. In addition, since Razadyne® was approved, 17 pharmaceutical companies that have filed ANDAs seeking to market generic copies of Razadyne®. Ten of these companies have further acquiesced in the validity of the '318 patent, certifying to FDA that they will not seek approval to market their generic copies until after that patent expires. They are Apotex Inc. (ANDA No. 77-781); Cobalt Pharmaceuticals, Inc. (ANDA No. 77-823); Eon Labs Manufacturing, Inc. (ANDA No. 77-607); IVAX Pharmaceuticals, Inc. (ANDA No. 77-609); Mutual Pharmaceuticals Co. (ANDA No. 77-586); Ranbaxy Laboratories Ltd. (ANDA No. 77-588); Roxane Laboratories, Inc. (ANDA No. 77-608); Sandoz Inc. (ANDA No. 77-589); Sun Pharmaceutical Industries, Ltd. (ANDA No. 77-592); and Watson Laboratories, Inc. (ANDA No. 77-767).

Finally, galantamine has proven to have many unexpected and surprising benefits from the perspective of one of skill in the art at the time of filing the application. In addition to the cognitive benefits provided by galantamine, the drug also reduces the neuropsychiatric disorders associated with Alzheimer's Disease, such as agitation and depression. Galantamine has been found to improve the activities of daily living of Alzheimer's patients and also to lighten the burden on caregivers. Evidence also suggests that galantamine delays nursing home placement. And it is the only cholinesterase

inhibitor shown in an FDA-reviewed pivotal trial to be effective in all four major trial outcomes – global, cognitive, functional, and behavioral.

In addition, galantamine has unexpectedly been discovered to promote cholinergic function not only through inhibition of cholinesterase, but also through allosteric modulation of the nicotinic receptor. This second mechanism of action for galantamine distinguishes it from all the other cholinesterase inhibitors and may well play an important role in promoting cognitive function and possibly slowing progression of Alzheimer's Disease.

In addition to experts who will be identified pursuant to Rule 26(a)(2) and the Court's Revised Scheduling Order of January 12, 2006 and the individuals identified in Plaintiffs' Rule 26(a)(1) initial and supplemental disclosures, Plaintiffs refer Defendants to the individuals identified in response to Interrogatory No. 12.

Interrogatory No. 16

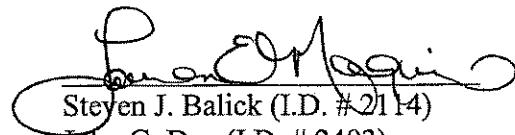
Describe the facts and circumstances regarding any licensing discussions and any actual or considered litigation between Plaintiffs and Waldheim Pharmazeutika GmbH regarding any United States or foreign patent(s) for the use of galantamine for the treatment of Alzheimer's disease or related dementia, including but not limited to any arguments set forth by Waldheim Pharmazeutika GmbH regarding any asserted invalidity of such patent(s), any actual or proposed settlement agreements, and any litigation outcomes, and identify all related documents and the five (5) most knowledgeable persons including that person's involvement, concerning the facts and circumstances.

Response:

In addition to the foregoing General Objections, Plaintiffs object to this interrogatory as intruding on matters covered by the attorney-client privilege and work product doctrine. Plaintiffs further object to this interrogatory because it seeks information that is irrelevant and immaterial to the matters involved in this action and is

not reasonably calculated to lead to the discovery of evidence that would be admissible herein. To the extent any non-privileged information exists concerning the subject matter of this interrogatory, and subject to Plaintiffs' relevance objection, Plaintiffs refer Defendants to the depositions of Dr. Bonnie Davis and Mr. John Richards and documents produced by Plaintiffs in this litigation which bear the Bates numbers SYN RAZ-0018791-804, SYN RAZ-0019713, SYN RAZ-0020089-103, JAN RAZ-0010903-15, JAN RAZ-0010949-50, JAN RAZ-0010965-80, JAN RAZ-0011208-22, JAN RAZ-0011228-34, JAN RAZ-0011244-46, and JAN RAZ-0011250-52.

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Dated: May 22, 2006

169716.1

CERTIFICATE OF SERVICE

I hereby certify that on the 22nd day of May, 2006, the attached **PLAINTIFFS**
JANSSEN PHARMACEUTICA N.V.'S, JANSSEN, L.P.'S, AND SYNAPTECH, INC.'S
OBJECTIONS AND RESPONSE TO DEFENDANTS TEVA PHARMACEUTICALS,
USA, INC.'S AND TEVA PHARMACEUTICAL INDUSTRIES LTD'S SECOND SET OF
INTERROGATORIES was served upon the below-named counsel of record at the address and
in the manner indicated:

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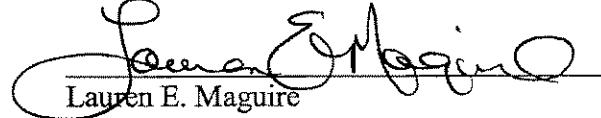
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VIA FEDERAL EXPRESS



Lauren E. Maguire

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: '318 PATENT) C.A. No. 05-356-KAJ
INFRINGEMENT LITIGATION) (consolidated)
)

NOTICE OF SERVICE

The undersigned hereby certifies that on the 22nd day of May, 2005, **PLAINTIFFS**
JANSSEN PHARMACEUTICA N.V.'S, JANSSEN, L.P.'S, AND SYNAPTECH, INC.'S
OBJECTIONS AND RESPONSE TO DEFENDANTS TEVA PHARMACEUTICALS,
USA, INC.'S AND TEVA PHARMACEUTICAL INDUSTRIES LTD'S SECOND SET OF
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/s/ Lauren E. Maguire

Lauren E. Maguire

Discovery Documents

1:05-cv-00356-KAJ In re: '318 Patent Infringement Litigation

U.S. District Court

District of Delaware

Notice of Electronic Filing

The following transaction was received from Maguire, Lauren entered on 5/22/2006 at 6:42 PM EDT and filed on 5/22/2006

Case Name: In re: '318 Patent Infringement Litigation

Case Number: 1:05-cv-356

Filer: Janssen Pharmaceutica N V

Janssen L P

Synaptech Inc.

Document Number: 212

Docket Text:

NOTICE OF SERVICE of Objections and Response to Defendants Teva Pharmaceuticals, USA, Inc.'s and Teva Pharmaceutical Industries LTD's Second Set of Interrogatories by Janssen Pharmaceutica N V, Janssen L P, Synaptech Inc..(Maguire, Lauren)

The following document(s) are associated with this transaction:

Document description: Main Document

Original filename: n/a

Electronic document Stamp:

[STAMP_dcecfStamp_ID=1079733196 [Date=5/22/2006] [FileNumber=217921-0]
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